DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-098/S-012

Abbott Laboratories
D-389, BLDG. AP30
200 Abbott Park Road
Abbott Park, Illinois 60064-6157

Attention: Micheal E. Sliwoski, M.S.,
Manager, Regulatory Affairs

Dear Mr. Sliwoski:

Please refer to your supplemental new drug application dated August 27, 1999, received September 1, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mivacron Injection (mivacurium chloride).

We acknowledge receipt of your submissions dated March 10, 2000, and November 6, 2000.

This supplemental new drug application provides for revisions in the CLINICAL PHARMACOLOGY: Special Populations: Geriatric Patients and PRECAUTIONS: Geriatric Use sections of the package insert.

We have completed the review of this supplemental application, as amended, and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted November 6, 2000).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-098/S-012." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Kimberly Compton, Project Manager, at (301) 827-7432.

Sincerely,

{See appended electronic signature page}

Cynthia McCormick, M.D.
Director
Division of Anesthetic, Critical Care,
and Addiction Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research